



Welcome to the September 2019 edition of *In A Capsule News!*

POPPIES—A PROUD TASMANIAN INDUSTRY

THE FACTS OF UNITED STATES COURT CASES AND THEIR IMPACT ON TASMANIAN POPPY PRODUCERS

A court in the US State of Oklahoma recently handed down a decision finding that Johnson and Johnson had helped fuel Oklahoma’s opioid crisis. Johnson and Johnson have been fined \$US572 million. This is the first case of at least 1,500 similar law suits. Although Johnson & Johnson are lodging an appeal, no doubt there will be more bad news to come for the U.S. legal narcotics industry, including the Purdue Pharma Chapter 11 Bankruptcy Filing and related matters.

Tasmania is receiving unwanted and unnecessary publicity and guilt by association, due to the fact Johnson & Johnson were sourcing some of their raw opiate material from Tasmanian farmers. Much, if not all, the adverse comments are based on misconceptions about the industry and Tasmania’s role in it.

Johnson & Johnson in their media statement following the court decision strongly defends its affiliate Jansson Pharmaceutical Company which manufactures final dosage/tablet pharmaceutical products. Johnson & Johnson’s statement can be found at <https://www.jnj.com/johnson-johnson-to-appeal-flawed-opioid-judgment-in-oklahoma>

As can be quite clearly understood from their statement the prescription medications at the centre of this case are derived from Fentanyl and Tapentadol both of which are laboratory made synthetic opioids, not opiate based medications with the raw material sourced from Tasmania.

Tasmania was drawn into the controversy when Brad Beckworth, one of the State of Oklahoma’s lawyers claimed that *“We know that the root of this entire crisis began in Tasmania and New Jersey with Johnson & Johnson”*

The State Attorney General, Mike Hunter, stated that Johnson & Johnson had been the principal origin for the active pharmaceutical ingredient in prescription opioids (mainly oxycodone and codeine) in the country for the last two decades through its then subsidiaries Noramco and Tasmanian Alkaloids.

Tasmania supplies the raw material for over 50% of the world’s demand for narcotic raw materials. Tasmanian farmers sell poppy straw to three companies. Two of these companies produced the narcotic raw material that was processed in the USA into one of the major drivers of addiction; oxycodone. Neither of these companies are now affiliates of Johnson and Johnson.

Tasmania is not the only supplier of raw materials to the U.S. Turkey and India are traditional suppliers with a guaranteed quota, while Spain is now a significant supplier in the U.S. The actual production of the poppy straw and production of raw materials for some of the products may have occurred in Tasmania, but it is too simplistic and erroneous to accuse Tasmania’s poppy growers of being complicit in some criminal conspiracy.

Tasmania should not have to bear the responsibility for American drug companies. Tasmanian produced raw materials are not solely sold to the U.S., but also to countries such as the United Kingdom, Norway and the European Union. This short article seeks to briefly point out the misconceptions and the facts.

THERE IS NOT A GLOBAL OVERUSE OF OPIATES

At the March 2019 meeting of the International Narcotics Control Board eminent medical and health professionals were united in calling for more – not less – access to opiates for pain relief. In essence opioid overuse is a first world problem, with the primary focus in the U.S., not in other less developed countries.

According to the International Narcotics Control Board (INCB) 1 in 10 of world population suffer from pain and opiate pain management is essential for palliative care. Opiates are the mainstay of cancer treatment and are indispensable in medicine and trauma treatment.

At the same time 80% of palliative care patients in need of controlled substance pain management lack access and 70% of global population have none or little access to controlled drugs for pain management .

The INCB reports that, despite global increases, global disparity and imbalance remain evident. North America is the region with the highest level of availability for consumption followed by Western and Central Europe. In all other regions, levels of availability for consumption are considerably lower.

INCB data shows the increase in availability for consumption is concentrated in high-income countries while, at the same time, availability for consumption has decreased and remains very inadequate in most countries in Africa and is inadequate in most countries in Asia, Central and South America, the Caribbean and Eastern Europe.

THE USA DEPENDENCY EPIDEMIC IS NOT BEING REPEATED WORLDWIDE

There is a need to distinguish between the USA and the rest of the world. The problems in the USA are not recent.

In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and healthcare providers began to prescribe them at greater rates.

In 2017, more than 70,000 Americans died as a result of an opioid overdose, including prescription opioids, heroin, and illicitly manufactured fentanyl,

Over-prescription, heavy marketing by company representatives and lax dispensing were not new problems. This is a long standing issue that was only started to be addressed in 2013 with President Obama’s **2013 National Drug Strategy**.

As a result the US tightened internal regulations which had the effect of dramatically reducing demand for all global imports, including those from Tasmania. This downward pressure has occurred since 2014.

Ongoing court cases in the U.S. should have no effect on current production levels in Tasmania.

For the past two seasons demand for opiate raw material has stabilised at approximately 12,000 hectares. Despite media concerns in the U.S. the current demand is sustainable for the production of legally and medically approved opiate based prescription drugs.

NOT ALL DRUGS ARE THE SAME

Opiates are not the sole cause of the 'epidemic'. Governments are concerned with opioid abuse but it is necessary to recognise that opiates are a very small group within the opioid group.

There is a need to distinguish between naturally plant based opiates, such as those derived from poppies, and opioids such as synthetic drugs manufactured in a laboratory.

Although it cannot be denied that oxycodone (an opiate marketed as Oxycontin) has been the cause of addiction and overdoses, much of the current concerns arise from synthetic drugs, often manufactured in illegal laboratories. The U.S. is facing an evolving problem, the first was abuse of prescription drugs, next came heroin and now Fentanyl in addition to methamphetamines and cocaine.

Fentanyl is 100 times more powerful than morphine and very effective if properly prescribed for severe pain. However, it is widely copied in illegal laboratories, often contaminated, and its illegal use, often mixed with heroin, is in epidemic proportions globally.

Synthetic opioids have surpassed prescription opioids as the most common drug class involved in overdose deaths in the United States, especially when combined with other prescription or illicit drugs such as heroin.

Among the more than 70,200 drug overdose deaths estimated in 2017 in the USA, the sharpest increase occurred among deaths related to fentanyl and fentanyl analogues (other synthetic narcotics) with more than 28,400 overdose deaths. This is not to say Australia has avoided the problem. Although there is little evidence here of illicit fentanyl deaths occurring in large numbers according to the National Coronial Information System, between 2013 and 2017 fentanyl was at least partly responsible for 230 opioid-related deaths.

TASMANIAN FARMERS AND TASMANIAN BASED COMPANIES OPERATE WITHIN A PROPER LEGAL FRAMEWORK

Tasmanian farmers: The Tasmanian poppy industry is recognised internationally by the International Narcotics Control Board (a United Nations organisation) as the gold standard for security and production. All farmers operate within Tasmanian laws and are overseen by the Tasmanian Poppy Advisory and Control Board. There has never been an instance of illegal diversion of poppies into heroin or morphine.

Tasmania Companies: Tasmanian Alkaloids was, until sold in 2016, an affiliate of Johnson and Johnson. It produced and supplied medical-grade ingredients for opiate pain medications. At every stage of the supply chain this company was governed by and complied with international and U.S. federal regulations and quotas. These included importation and manufacturing quotas established by the U.S. Drug Enforcement Administration (DEA) and United States Food and Drug Administration FDA.

Tasmanian Alkaloids played no role in the manufacturing, sales or marketing of the finished product in the U.S. United States prosecutors have claimed the problems were caused by American companies within the U.S. over-zealously marketing, turning a blind eye towards the dangers of addiction and possessing a less than moral attitude to prescriptions. But this has occurred in the USA and is clearly out of the hands of Tasmania's farmers!

THOSE WHO CRITICISE OR COMMENT ARE NOT ALWAYS WELL-INFORMED

Unfortunately many who comment do not understand even the basics of the industry. How many times have we heard of Tasmania growing opium when we use concentrate of poppy straw technology (almost impossible to divert to the illicit market)?

Using Tasmania and Afghanistan in the same statement is equally insulting. The 2018 INCB report shows that in 2017 the illicit opiate economy in Afghanistan (opium and heroin) substantially surpassed the level of the country's licit export of goods and services. Tasmania has a well-regulated and safe industry. It is not a narco-state!

Some Members of Parliament have urged the Tasmanian industry to reconsider dealing with Johnson and Johnson even when aware that Johnson and Johnson sold its Tasmanian affiliates in 2016.

Tasmania should continue to produce, process and market a legal and much-needed product while the United States, through the DEA, the FDA and the legal system, continue to strongly regulate its internal affairs.

The Tasmanian poppy industry and farmers shouldn't be subjected to ill-informed and senseless comments. Hopefully, the above summary of the world situation will help in rebutting such nonsense.

CONCLUSION

There can be no doubt that some major U.S. pharmaceutical companies face allegations that they have been criminally negligent in their practices. When combined with a previous lax regulatory system for prescriptions and the naivety of some doctors this has led the United States into an epidemic of drug dependency and deaths. However, to simply place Tasmanian farmers in the same moral category as some major pharmaceutical companies is to ignore the facts and the constant supervision by the INCB over the Tasmanian industry.

Throughout the decades of poppy growing in Tasmania the United Nations, through the INCB, has never questioned or criticised the Tasmanian industry. It still looks to Tasmania as the safest and most reliable supplier to the world of much needed medical opiates.

Throughout the continuing controversy, as major drug companies are brought to account for deceptive marketing, Tasmanian farmers can rest assured they are contributing to a necessary and vital demand for legitimate pain relief for millions. There can be no thought that Tasmanian farmers bear any responsibility for the wrong doing of others.

- *US opioid crisis ruling leads to \$845 million fine for drug maker Johnson & Johnson in Oklahoma.* ABC news. 27 August 2019. [https://www.abc.net.au/news/2019-08-27/johnson-&-johnson-ordered-to-pay-\\$844m-over-opioid-drug/11451758](https://www.abc.net.au/news/2019-08-27/johnson-&-johnson-ordered-to-pay-$844m-over-opioid-drug/11451758)
- *2018 Report International Narcotics Control Board.* https://www.incb.org/documents/Publications/AnnualReports/AR2018/Supplement/05_Chapter_II.pdf
- *B. Yasgur.* Medscape 1 May 2018. <https://www.medscape.com/viewarticle/896000>
- *National Institute of Drug Abuse* <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>
- *National Drug and Alcohol Research Centre—Opioid-, amphetamine-, and cocaine-induced deaths in Australia: August 2018* <https://ndarc.med.unsw.edu.au/sites/default/files/Drug%20Induced%20deaths%20August%202018%20Drug%20Trends%20Bulletin.pdf>

Co-authored by:

The Hon Peter Patmore AM, PhD, LLB

2003-2015: Chairman, Poppy Advisory and Control Board of Tasmania.

2003-2015: Australian Delegate to the United Nations Conference on Narcotic Drugs, Vienna.

2006: Represented Tasmanian and Australian Governments in Washington DC. Prepared and presented appeal brief opposing changes to the US administrative rules allowing additional countries to export narcotic raw materials to the US. The meetings and presentation of appeal was with the DEA, Drug and Chemical Analysis Section and the Secretary of the United States Senate Caucus Committee on International Narcotics Control.

2004-2005: Chair of United Nations International Narcotics Control Board Expert Group. The brief was to review a technical study on the relative merits of different methods of producing opiate raw material. The Report was published in January 2005.

Keith Rice, Chief Executive, Poppy Growers Tasmania Inc (PGT)

- Represented PGT at the United Nations Commission on Narcotic Drugs from 1994—2019.
- Represented PGT at the United States Judiciary Committee, Subcommittee on Crime, Hearing into the US 80/20 Import Rule in 1991.